DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 17, 2015

Stryker Endoscopy
Ms. Kelly Kucharczyk
Associate Manager, Regulatory Affairs
5900 Optical Court
San Jose, California 95138

Re: K150416
Trade/Device Name: ProCinch Adjustable Loop Device
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY
Dated: February 19, 2015
Received: February 20, 2015

Dear Ms. Kucharczyk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K150416

The Stryker ProCinch Adjustable Loop Fixation Device is intended for the fixation of bone-to-bone or soft tissue-to-bone as fixation posts, a distribution bridge, or for distributing suture tension during Anterior Cruciate Ligament (ACL) and Posterior Cruciate Ligament (PCL) Repair and Reconstruction.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

I. SUBMITTER

Stryker Endoscopy
5900 Optical Ct
San Jose, CA 95138

Contact Person: Kelly Kucharczyk, RAC
Associate Manager, Regulatory Affairs

Date Prepared: April 16, 2015

Phone: 810-813-4672
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II. DEVICE

Name of Device: Stryker ProCinch Adjustable Loop Device (Models: Standard Tensioning, Reverse Tensioning)

Common Name: Pin, Fixation, Smooth

Classification Name: Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040

Regulatory Class: II

Product Code: HTY

III. PREDICATE DEVICE

Arthrex ACL TightRope, K112990
This predicate has not been reported by the manufacturer as being subject to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

Stryker Endoscopy is introducing the Stryker ProCinch Adjustable Loop device for use in orthopedic applications. The Stryker ProCinch Adjustable Loop Device is a cortical suspensory fixation implant that consists of an adjustable nonabsorbable suture loop assembled to a titanium button. The device is offered in two configurations, Standard Tensioning and Reverse Tensioning.

V. INDICATIONS FOR USE

The Stryker ProCinch Adjustable Loop Fixation Device is intended for the fixation of bone-to-bone or soft tissue-to-bone as fixation posts, a distribution bridge, or for distributing suture tension during Anterior Cruciate Ligament (ACL) and Posterior Cruciate Ligament (PCL) Repair and Reconstruction.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Stryker ProCinch Adjustable Loop Fixation Device is substantially equivalent to other commercially available cortical suspension fixation devices in regard to intended use, design, materials of construct, performance attributes, and operational principles. The Arthrex ACL TightRope Device has been identified as an appropriate predicate.

VII. PERFORMANCE DATA

Non-clinical bench testing was performed to verify the efficacy of the Stryker ProCinch Adjustable Loop Device as compared to the predicate. This testing included Cyclic Extension and Ultimate Tensile Strength after cyclic loading. The results of this testing verified that the subject device performs statistically equivalent or better than the predicate device. Clinical testing was not required to demonstrate substantial equivalence for this submission.

VIII. CONCLUSIONS

The information presented within this traditional premarket submission demonstrate that the Stryker ProCinch Adjustable Loop Device is substantially equivalent to the predicate device and should perform as designed within its intended use.